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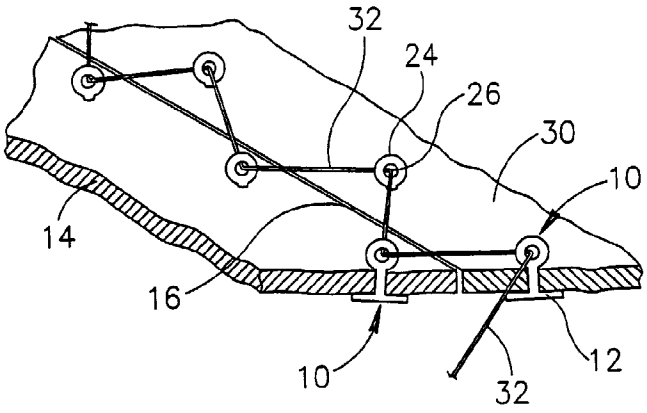
(54) Title: SUTURING SYSTEM



(57) Abstract: A system and method for suturing is provided, wherein a plurality of separate anchor members each having an anchoring end and a non-anchoring end, are adapted to individually and sequentially enter pierced tissue on both sides of an incision. The anchor members have a plurality of suture-retaining forms at their non-anchoring ends, and a suturing filament in contact with the suture-retaining forms, whereby tautening of the suture filament engaging a plurality of said anchor members serves to approximate tissue on both sides of an incision irrespective of the spacing between respective anchor members.

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SUTURING SYSTEM

FIELD OF THE INVENTION

The present invention relates to an improved suturing system. More particularly, the present invention provides a system using anchor members which project outward beyond an incision or wound being closed, and receive a suture filament which engages the same.

BACKGROUND OF THE INVENTION

Surgical suturing is carried out to join opposing tissue, to repair cuts, lacerations and surgical incisions, as well as to connect internal organs such as for forming an anastomosis between bowel ends, intra-abdominal surgery, hepatoraphy, and splenoraphy for example. There are records indicating that suturing was carried out on patients during the time of the Roman Empire, with surgeons closing fascia using needle and thread in a manner similar to that used to repair clothing. This time-honored method, while still in use, requires a disproportionate amount of time and effort often at the end of a long and demanding surgical procedure. It is a stage in the surgery where the surgeon or his assistants are occasionally injured by inadvertent needle puncture, a major concern of medical personnel in the present era of AIDS. Furthermore, the reported incidence of post-operative hernias using this method varies between 9% - 19%, indicating that present methods of abdominal fascia closure require improvement.

Stapling is a known alternative to suturing, and much effort has been made to develop suitable staples and application tools. The major drawback therein is that the surgeon cannot vary the distance between the staple prongs, nor can tension be adjusted after the staples are in place. Such limitations are felt particularly when the thickness and strength of the tissue being joined varies along its length.

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An integral anchor and filament for deep insertion into tissue is disclosed by Richards et al in US Patent no. 4,669,473. During insertion the sharp-ended rigid anchor member is held disposed nearly coaxially to the filament member. After deployment the anchor tends to take up an orientation of 90 degrees to the filament and then provides substantial resistance to filament pull-out.

A major improvement in suturing procedures was achieved by the development of anchor members implanted during suturing and connected to a discrete suturing filament. A hand held, hand operated suturing gun is used for piercing the tissue and implanting the anchor member. The suturing filament is connected to the anchor members already before loading into the gun, so that anchor implantation and filament application is carried out simultaneously. A system of this type is disclosed by Hayhurst in US Patent no. 5,810,848. The surgeon pauses between consecutive anchor insertions in order to tense the suturing filament, as such action is difficult or impossible to carry out after further anchor members are implanted and the suture filament is no longer readily accessible, or even if accessible would require tension too high for the resistance by the anchor nearest the end whereon tension is applied. It is disadvantageous that filament tension cannot be adjusted or varied at the conclusion of the procedure.

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SUMMARY OF THE INVENTION

It is one of the objects of the present invention to provide an anchor member which allows manipulation of a suturing filament after implantation of the anchors.

It is a further object of the present invention to provide a rapid-fire suturing gun for fast insertion of said anchor members.

There is provided, in one embodiment of the present invention, a plurality of separate anchor members each having an anchoring end and a non-anchoring end, adapted to individually and sequentially enter pierced tissue on both sides of an incision and to be retained in the tissue, a plurality of suture-retaining forms provided at the non-anchoring ends of the anchor members fashioned to protrude from the anchored tissue, and a suturing filament in contact with the plurality of suture-retaining forms. Tautening of the suture filament serves to approximate tissue on both sides of an incision irrespective of the spacing between respective anchor members.

There is provided, in another embodiment of the present invention, a suturing gun having a sharpened end member for entering tissue, a plurality of separate anchor members each having an anchoring end and a non-anchoring end, adapted to individually and sequentially enter pierced tissue on both sides of an incision together with the sharpened end member of the suturing gun and to be retained in the tissue after the withdrawal of the sharpened end member, a plurality of suture-retaining forms provided at the non-anchoring ends of the anchor members fashioned so as to protrude from the anchored tissue, and a suturing filament in contact with the plurality of suture-retaining forms. Tautening of the suture filament serves to approximate tissue on both sides of an incision irrespective of the spacing between respective anchor members.

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In a further embodiment of the present invention there is provided a method for suturing tissue, including the steps of piercing the tissue with a suturing gun adapted to dispense anchor members each having a suture-retaining form individually and sequentially on two sides of an incision, inserting a suturing filament into the suture retaining forms, and tautening the suturing filament so as to approximate tissue on both sides of the incision.

There is provided in another embodiment of the present invention, a method for suturing tissue, including the steps of piercing the tissue with a suturing gun adapted to dispense individually and sequentially on two sides of an incision anchor members each having a suture-retaining form wherein the suture retaining forms have a pre-threaded suturing filament, and tautening the suturing filament so as to approximate tissue on both sides of the incision.

Yet further embodiments of the invention will be described hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in connection with certain preferred embodiments with reference to the following illustrative figures so that it may be more fully understood.

With specific reference now to the figures in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those

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skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1 is a perspective view of a preferred embodiment of the suturing system according to the invention;

FIG. 2 is a perspective view of a similar embodiment wherein the anchor members are provided with hooks;

FIG. 3 is a plan view of the system being used for hepatoraphy;

FIG. 4 is a perspective view of a suturing system including a suturing gun;

FIG. 5 is a perspective view of anchor members provided with long apertures for filament retention;

FIG. 6 is a sectional elevational view of an embodiment wherein the anchor members are interconnected;

FIG. 7 is a sectional view of a system being used for laparoscopy;

FIG. 8 is a sectional elevational view of an electrically powered manually actuated suturing gun;

FIG. 9 is a perspective view of a bowel which has been repaired using the system;

FIG. 10 is an elevational view of a further embodiment of the anchor member;

FIG. 11 is a perspective view of a suturing system using staples;

FIG. 12 is an elevational view of a staple as used in the previous figure;

and

FIG. 13 is the same as FIG. 12, after the staple has been deformed for retention purposes.

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DETAILED DESCRIPTION OF THE INVENTION

There is seen in FIG. 1 a suturing system comprising a plurality of separate anchor members 10. Advantageously, the anchor members are made of biodegradable material absorbable by living human or animal tissue so that there is no need for their removal after healing. Materials known in the prior art which meet these requirements are, for example, polylactide copolymers and glycolide copolymers, as well as collagen based materials.

Each anchor member 10 has an anchoring end 12 adapted to individually and sequentially enter pierced tissue 14 on both sides of an incision 16 together with a sharpened end member 18 of a suturing gun 20, to be described with reference to FIG. 4.

The anchor members 10 are each provided at their non-anchoring ends 24 with a suture-retaining form 26, which in the present embodiment is an aperture.

The anchor members 10 are configured to allow protrusion of the suture-retaining form 26 from the anchored tissue to extend in the present embodiment beyond an outer fascial surface 30. Whether the anchor is used internally or externally, the anchor member 10 is always sized to enable the suture-retaining form to protrude from the anchored tissue 14 and to enable engagement with a suturing filament 32 drawn into contact with the suture-retaining form 26.

In the present embodiment, suture-retaining form 26 is in the form of an aperture, and the suturing filament 32 is sequentially pre-threaded through the apertures during manufacture thereof.

After all the anchor members 10 are in place, tautening of the suture filament 32 engaging a plurality of the anchor members 10 serves to approximate tissue 14 on both sides of the incision 16 relative to each other, irrespective of the spacing between respective anchor members. That is, the tissue 14 on each side of the

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incision 16 is lined up and in contact with the tissue 14 on the other side of the incision 16 so that healing can take place.

While the shown embodiment illustrates diagonal stitching, there is no difficulty in executing square stitching by appropriate positioning of the anchor members 10.

With regard to the rest of the figures, similar reference numerals have been used to identify similar parts.

Referring now to FIG. 2, there is seen a detail of a possible further embodiment of a suturing system according to the present invention, wherein the suture-retaining form 26 is a hook. The anchor members 10 are inserted before being connected to the suturing filament 32. After implantation the surgeon knots the suturing filament 32 to one of the anchor members 10, or anchors the suturing filament 32 by needle sewing. The surgeon then approximates tissue on both sides of the incision 16 relative to each other by tautening the suturing filament 32. The surgeon can connect the anchors in any manner: diagonally, square, or crisscross. Should the result not be satisfactory, the suturing filament 32 is easily removed and another pattern can be used.

The suturing filament 32 used over an outer skin surface in the present embodiment is non-biodegradable, for example surgical silk, stainless steel, polyamide, or polypropylene, and may be selected according to the user's personal preferences. The suturing filament 32 is removed after the opening has healed.

FIG. 3 illustrates an internal application, hepatoraphy in the present example. Anchor members 10 are configured to allow protrusion of the suture-retaining form 26 from the anchored tissue 14 to extend into a body cavity other than the cavity presently under repair, in the present example the liver 42. Biodegradable materials are used both for the anchor members 10, as described with

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reference to FIG. 1, and the suturing filament 32. The suturing filament 32 is made of biodegradable material absorbable by living human or animal tissue.

Suitable materials for the anchor members 10 and the suturing filament 32 commercially available include surgical gut made of purified collagen, polyglactin 910 (trade name: VICRYL), polydioxanone (PDS), and poliglecaprone 25 (trade name: MONOCRYL). The suturing filament 32 is slowly attacked by body enzymes or is hydrolyzed in the body tissue. This process takes a number of weeks, sufficient time for the tissues to heal.

Seen in FIG. 4 is a suturing system including a suturing gun 20 known in the prior art.

The gun is provided with a sharpened end member 18 adapted to pierce tissue on both sides of an incision 16. The gun 20 holds a supply of anchor members 10, as described with reference to FIG. 1. After the tissue 14 is pierced the surgeon operates a control lever 22 to deposit an anchor member 10, which is retained in the tissue 14. The sharpened end member 18 of the gun 20 is then withdrawn. The gun 20 is adapted to carry, dispense and implant a plurality of anchor members 10, which may conveniently be stored in a cassette 46 with or without a pre-threaded suturing filament 32.

Referring now to FIG. 5, there is depicted a pair of anchor members 10 which are pre-threaded with the suturing filament 32. The suture-retaining form 26 is an elongated oval, which is well adapted for use on tissue of varying thickness.

FIG. 6 shows a detail of a suturing system wherein the anchor members 10 are detachably interconnected with adjacent anchor members 10. In use, each anchor member 10 is separated immediately prior to insertion by the suturing gun 20. Before use the anchor members 10 form a chain which is easily and quickly loaded into the gun 20. An insertion finger 60 in the gun 20 pushes the leading anchor member 54a forward at its anchoring end 12. This movement

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causes rupture of a thin section 58 between adjacent anchor members, for example anchor member 10a and 10b. The anchoring end 12 is displaced into parallel alignment (not shown) with the non-anchoring end 24. The resiliency of the non-anchoring end 24 will cause the anchoring end 12 to restore the original perpendicular alignment between anchoring end 12 and non-anchoring end 24, while the adjacent anchor member 10b is retained by a movable tooth 62. The suturing filament 32 is shown pre-assembled to the anchor members 10.

FIG. 7 illustrates a suturing system wherein the anchor members 10 are configured to allow protrusion of the suture-retaining form 26, seen in FIG. 1, from the anchored tissue to extend into a body cavity 63 other than a cavity presently being closed by the suturing system. The suturing gun 20 has an elongated barrel 66 which can be inserted through a standard laparoscopic trocar 68 and manipulated therethrough. The figure shows intra-abdominal suturing in progress. Thus, it is apparent that the system can be used for endoscopic surgery as well as other forms of surgery.

Seen in FIG. 8 is an electric suturing gun 70 suitable for use as part of a suturing system. The electric suturing gun may provide rapid-fire capabilities so as to facilitate faster suturing.

The gun 70 is electrically powered by a solenoid 72 rigidly retained inside the gun body, and dispenses an anchor member 10 when operated by means of a push button 74 on an outer face of the gun 70. A sharp tip 76 of the gun 70 is manually inserted into the tissue, whereafter the surgeon presses the button 74 energizing the solenoid 72 to draw a pusher arm 78 towards the sharp tip 76 while advancing an anchor member 10 thereto. The solenoid 72 also operates a crank lever 80 which lowers a retaining tooth 82 to allow the next anchor member 10 to come into position. After anchor member 10 is inserted in the tissue, a tension spring 84 returns the mechanism to its original position. The electrically powered gun 70 eliminates the need for a hand operating lever 22 as

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shown in FIG. 4. To enhance safety, the power supply is low voltage, preferably 24 volt.

FIG. 9 shows the suturing system being used for forming an anastomosis between two ends of a bowel 100, according to a further embodiment of the present invention.

FIG. 10 illustrates a T type anchor member 10, which can be used for application of suturing filament 32 after all the anchor members 10 are in place. The anchoring end 12 is the same as that seen in FIG. 1. The suture-retaining form 26 is a cross.

As stapling guns have been well developed, the present invention also discloses a staple which is used in the same manner as the anchor members. In contradistinction to prior art staples, the staple is used to anchor the suturing filament and not directly to bridge the tissue edges being joined. The tissue-piercing ends of the staple are bent after insertion to insure firm retention.

Referring now to Figs. 11, 12 and 13 taken together, there is seen a suturing system including a plurality of separate anchor members 10 in the form of a staple. Each anchor member 104 has a pair of spaced-apart tissue-piercing ends 106 connected by a web portion 108. As during insertion the staple leg ends 106 are parallel to each other, they are adapted to individually and sequentially enter, and after deformation be retained by tissue 110 on both sides of an incision 112.

The web portion 108 of each anchor member 10 is provided with a suture-retaining form 26, which in the present embodiment is a ring. The anchor member 10 is sized to protrude from the stapled tissue 110, shown in the drawing as an abdominal fascial closure. This projection makes possible the application of and the passage therethrough of suturing filament 32. In the

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shown embodiment the suturing filament 32 has been inserted through the suture-retaining form 26 before loading the prior-art suturing gun 20.

Tautening of the suturing filament 32 engaging a plurality of anchor members 10 serves to approximate tissue on both sides of the incision 112 relative to each other irrespective of the spacing between respective anchor members 10.

Before withdrawal of the suturing gun 20, a pair of arms 120 supported by the gun 20 bend the tissue-piercing ends 106 of the anchor member 10 towards each other to improve retention of the anchor member 10 in the tissue, as shown before and after bending in Figs. 12 and 13 respectively.

In a further embodiment of the present invention, the anchor members 10 are rivets. The anchor members 10 may be any retaining form, and the suture-retaining form 26 may be of any shape suitable to retaining a suturing filament 32, either pre-threaded or threaded during surgery.

It will thus be realized that the novel anchor members of the present invention serve to allow tensioning of the suturing filament to the degree decided by the surgeon. The loops, hooks or apertures at the anchor extremity act as pulleys to evenly distribute tension. This alleviates stress concentration on an individual anchor, and is expected to achieve a reduction in post-operative hernias.

A needle can be used for anchoring the filament, but the needle need not be pushed continuously and sequentially into the tissue and retrieved therefrom as in standard needle and thread suturing, so inadvertent injury to the surgeon or assistants is avoided, and time and effort required for closure are greatly reduced.

While the examples described refer to the joining of living tissue, the anchor members of the present invention may also be used for connecting netting to

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tissue, as is commonly carried out during the repair of external hernias when part of the bowel or other organ projects through a muscular wall.

It will be evident to those skilled in the art that the invention is not limited to the details of the foregoing illustrative embodiments and that the present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

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WHAT IS CLAIMED IS:

1. A suturing system comprising:

a plurality of separate anchor members each having an anchoring end and a non-anchoring end, said anchor members adapted to individually and sequentially enter pierced tissue on both sides of an incision and to be retained in said tissue;

a plurality of suture-retaining forms provided at said non-anchoring ends of said anchor members wherein said suture-retaining forms are fashioned so as to protrude from the anchored tissue; and

a suturing filament in contact with said plurality of suture-retaining forms, whereby tautening of said suture filament engaging a plurality of said anchor members serves to approximate tissue on both sides of an incision irrespective of the spacing between respective anchor members.

2. A suturing system according to claim 1, wherein said suture-retaining form is an aperture.

3. A suturing system according to claim 1, wherein said suture-retaining form is a hook.

4. A suturing system according to claim 1, wherein said suture-retaining form is a cross.

5. A suturing system according to claim 1, wherein said anchor members are staples.

6. A suturing system according to claim 1, wherein said anchor members are rivets.

7. A suturing system according to claim 1, wherein said suturing filament is made of biodegradable material absorbable by living human or animal tissue.

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8. A suturing system according to claim 1, wherein said anchor members are made of biodegradable material absorbable by living human or animal tissue.

9. A suturing system according to claim 1, wherein said anchor members are configured to allow protrusion of said suture-retaining form from said anchored tissue to extend into a body cavity other than a cavity presently being closed by said suturing system.

10. A suturing system according to claim 1, wherein said anchor members are configured to allow protrusion of said suture-retaining form from said anchored tissue to extend beyond an outer tissue surface.

11. A suturing system comprising:

a suturing gun having a sharpened end member for entering tissue;

a plurality of separate anchor members each having an anchoring end and a non-anchoring end, said anchor members adapted to individually and sequentially enter pierced tissue on both sides of an incision together with said sharpened end member of said suturing gun and to be retained in said tissue after the withdrawal of said sharpened end member;

a plurality of suture-retaining forms provided at said non-anchoring ends of said anchor members wherein said suture-retaining forms are fashioned so as to protrude from the anchored tissue; and

a suturing filament in contact with said plurality of suture-retaining forms, whereby tautening of said suture filament engaging a plurality of said anchor members serves to approximate tissue on both sides of an incision irrespective of the spacing between respective anchor members.

12. A suturing system according to claim 11, wherein said anchor members are pre-threaded with said suturing filament.

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13. A suturing system according to claim 11, wherein said anchor members are detachably interconnected with adjacent anchor members, each anchor member being separated immediately prior to insertion by said suturing gun.

14. A suturing system according to claim 11, wherein said anchor members are configured to allow protrusion of said suture-retaining form from said anchored tissue to extend into a body cavity other than a cavity presently being closed by said suturing system.

15. A suturing system according to claim 14, wherein said gun has an elongated barrel which can be inserted through a standard laparoscopic trocar and manipulated therethrough.

16. A suturing system comprising a plurality of separate anchor members each having a pair of spaced-apart tissue-piercing ends connected by a web portion and adapted to individually and sequentially enter and be retained by tissue on both sides of an incision, characterized in that the web portion of each of said anchor members is provided with a suture-retaining form sized to protrude from the pierced tissue and to enable the passage therethrough of a suturing filament, whereby tautening of said suturing filament engaging a plurality of said anchor members serves to approximate tissue on both sides of an incision relative to each other irrespective of the spacing between respective anchor members.

17. A suturing system according to claim 16 wherein said anchor members are staples.

18. A method for suturing tissue, the method comprising the steps of:

piercing said tissue with a suturing gun adapted to dispense anchor members each having a suture-retaining form individually and sequentially on two sides of an incision;

inserting a suturing filament into said suture retaining forms; and

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tautening said suturing filament so as to approximate tissue on both sides of said incision.

19. A method as in claim 18 wherein said step of piercing is done rapidly.

20. A method for suturing tissue, the method comprising the steps of:

piercing said tissue with a suturing gun adapted to dispense individually and sequentially on two sides of an incision anchor members each having a suture-retaining form wherein said suture retaining forms have a pre-threaded suturing filament; and

tautening said suturing filament so as to approximate tissue on both sides of said incision.

21. A method as in claim 20 wherein said step of piercing is done rapidly.

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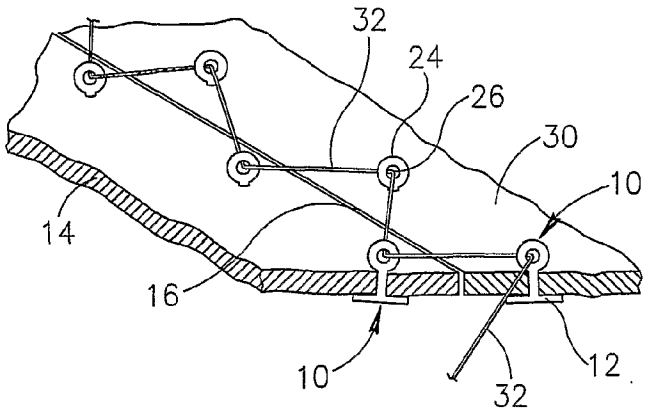

FIG.1

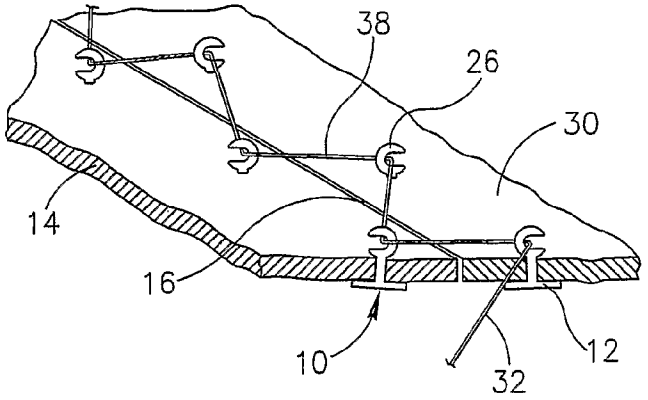

FIG.2

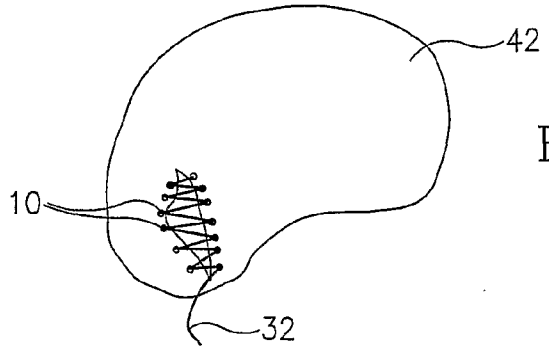

FIG.3

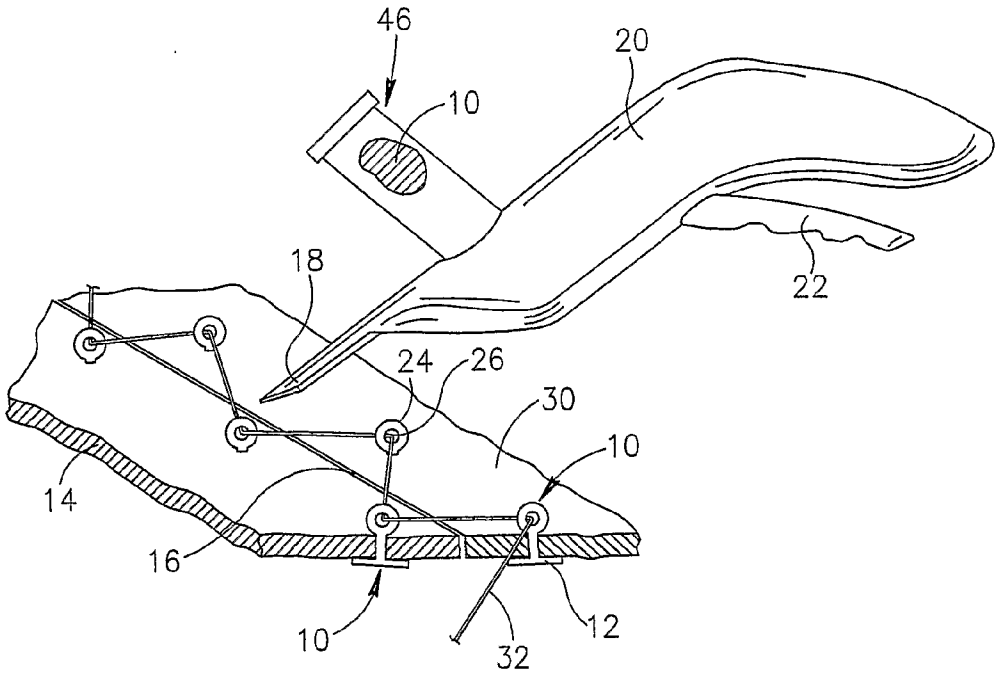

FIG.4

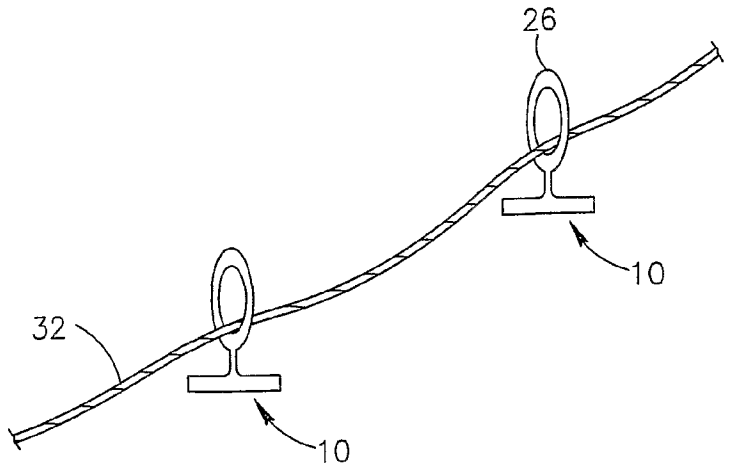

FIG.5

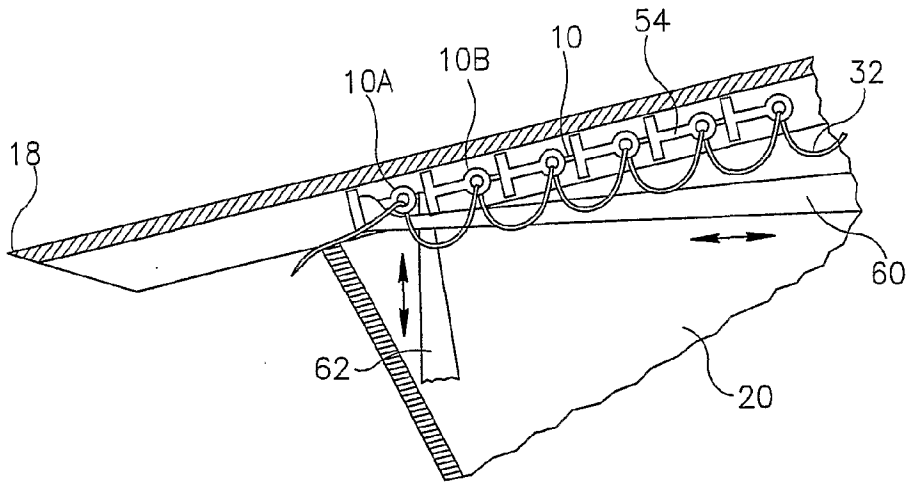

FIG.6

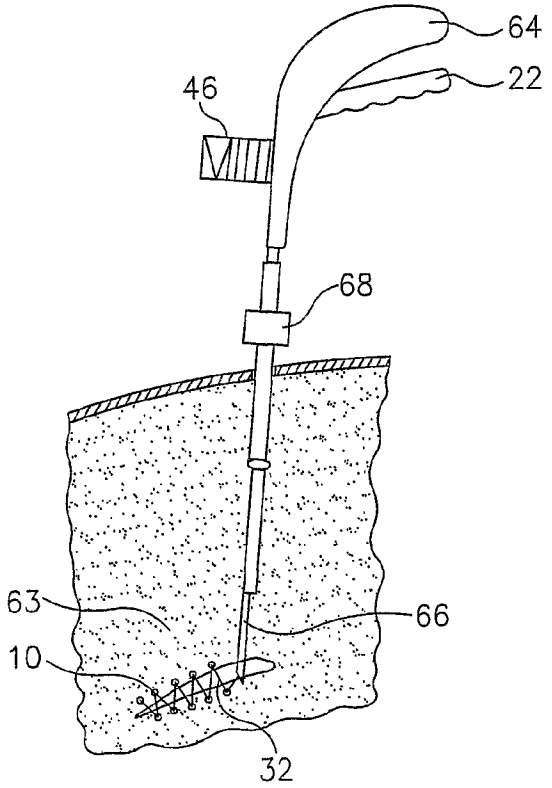

FIG.7

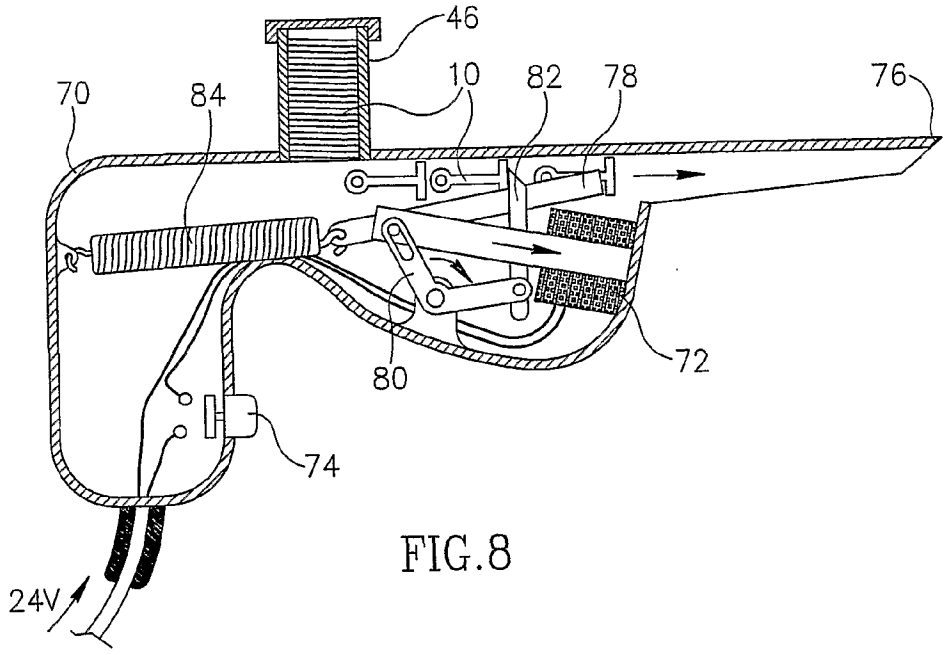

FIG.8

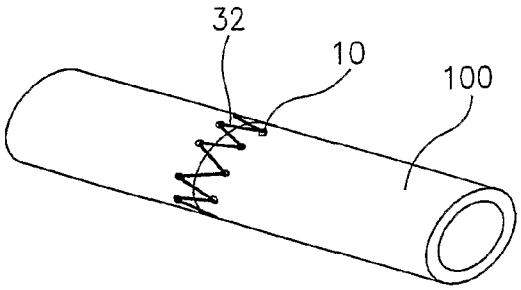

FIG.9

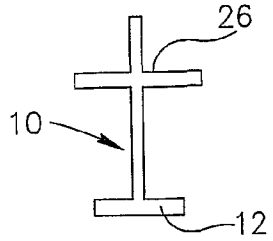

FIG.10

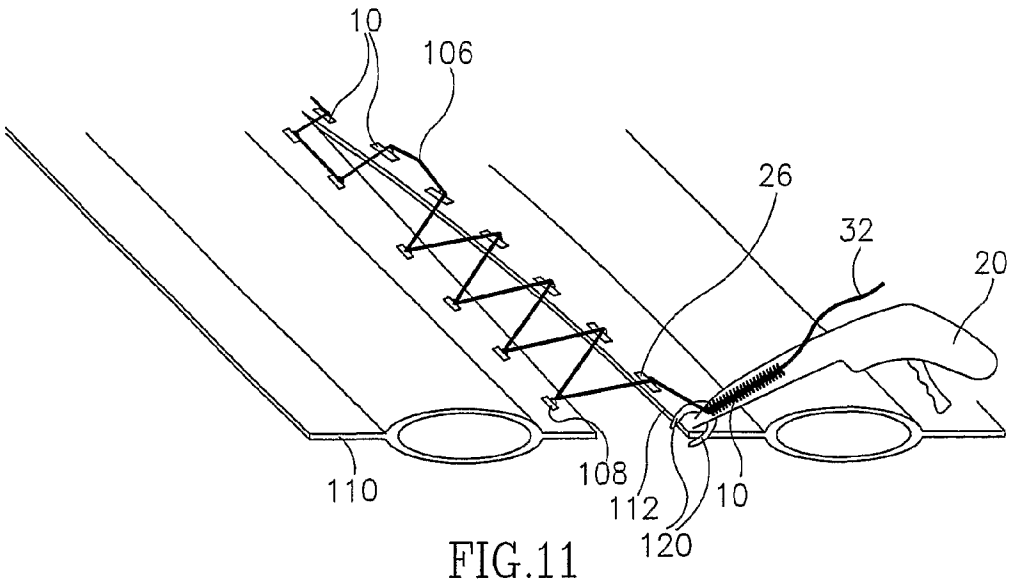

FIG.11

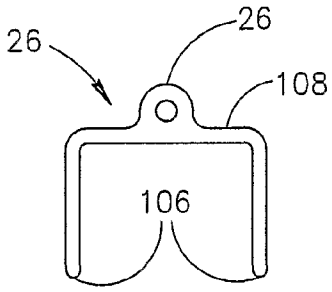

FIG.12

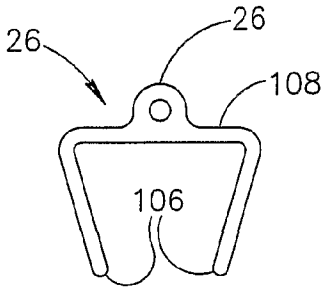

FIG.13